

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

ANTHONY STEEN,

Plaintiff,

v.

MEDTRONIC, INC.,

Defendant.

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Civil Action No. **3:10-CV-936-L**

MEMORANDUM OPINION AND ORDER

Before the court is Defendant Medtronic, Inc.'s Motion to Dismiss, filed May 17, 2010. Plaintiff Anthony Steen ("Plaintiff") did not file a response or otherwise object to the motion. After consideration of the filings, record, and applicable law, the court **grants** Defendant Medtronic, Inc.'s Motion to Dismiss.

I. Factual and Procedural Background

Plaintiff originally filed this products liability action in the 160th Judicial District Court of Dallas County, Texas, on April 14, 2010. Defendant Medtronic, Inc. ("Defendant") removed the action to this court on May 10, 2010, on the grounds that diversity of citizenship existed between the parties and that the amount in controversy exceeded \$75,000, exclusive of interest and costs.

This action arises out of injuries that Plaintiff allegedly sustained when his implanted Medtronic Adapta Pacemaker, a device manufactured by Defendant, became dislodged and punctured the right atrium of Plaintiff's heart. Plaintiff contends that his injuries were caused by a product malfunction and asserts products liability claims for strict liability, negligence, and breach of warranty. Plaintiff seeks to recover compensatory damages for past and future medical care,

physical pain and suffering, impairment, loss of earning capacity, mental anguish, and exemplary damages.

Defendant has moved for dismissal of Plaintiff's claims pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted. Alternatively, Defendant argues that Plaintiff's claims should be dismissed because they are preempted by federal law.

II. Standard for Rule 12(b)(6) - Failure to State a Claim

To defeat a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 742 (5th Cir. 2008); *Guidry v. American Pub. Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007). A claim meets the plausibility test "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (internal citations omitted). While a complaint need not contain detailed factual allegations, it must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation omitted). The "[f]actual allegations of [a complaint] must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* (quotation marks, citations, and footnote omitted).

In reviewing a Rule 12(b)(6) motion, the court must accept all well-pleaded facts in the complaint as true and view them in the light most favorable to the plaintiff. *Sonnier v. State Farm*

Mutual Auto. Ins. Co., 509 F.3d 673, 675 (5th Cir. 2007); *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). In ruling on such a motion, the court cannot look beyond the pleadings. *Id.*; *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999), *cert. denied*, 530 U.S. 1229 (2000). The pleadings include the complaint and any documents attached to it. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000). Likewise, “[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to [the plaintiff’s] claims.” *Id.* (quoting *Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993)).

The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when it is viewed in the light most favorable to the plaintiff. *Great Plains Trust Co. v. Morgan Stanley Dean Witter*, 313 F.3d 305, 312 (5th Cir. 2002). While well-pleaded facts of a complaint are to be accepted as true, legal conclusions are not “entitled to the assumption of truth.” *Iqbal*, 129 S.Ct. at 1950 (citation omitted). Further, a court is not to strain to find inferences favorable to the plaintiff and is not to accept conclusory allegations, unwarranted deductions, or legal conclusions. *R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005) (citations omitted). The court does not evaluate the plaintiff’s likelihood of success; instead, it only determines whether the plaintiff has pleaded a legally cognizable claim. *United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004).

III. Analysis

A. Failure to State a Claim Upon Which Relief can be Granted

Defendant argues that Plaintiff has failed to state a claim upon which relief can be granted because Plaintiff's Original Petition does not allege sufficient facts to support his asserted claims for relief. The court agrees.

With respect to his strict liability claim, Plaintiff simply states that Defendant manufactured and sold a defective and unsafe product. Plaintiff makes no factual allegations showing *how* the pacemaker was "defectively designed and unreasonably dangerous." Pl.'s Original Pet. 4 ¶ 12. Although Plaintiff alleges in conclusory fashion that the pacemaker's defective design caused it to dislodge and cause Plaintiff's injuries, a complaint must set forth "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citation omitted). Plaintiff has not stated a strict liability claim upon which relief can be granted, and that claim will be dismissed.

With respect to his negligence claim, Plaintiff alleges multiple alternative legal conclusions relating to Defendant's due care, manufacture, and design. Although he states that Defendant's attention to these matters was deficient, Plaintiff alleges no facts in support of such deficiencies. The "[f]actual allegations of [a complaint] must be enough to raise a right to relief above the speculative level" *Id.* Plaintiff further asserts the doctrine of *res ipsa loquitur* and argues that the design of the pacemaker was exclusively within the control of Defendant, that Plaintiff had no means of ascertaining the method of the product's design, and that the pacemaker was in the same condition it was in when it left the control of Defendant. The court disagrees.

By Plaintiff's own admission, the pacemaker was implanted by an unnamed doctor at Baylor Medical Center at Irving on June 26, 2008. Pl.'s Original Pet. 3 ¶ 10. Plaintiff's limited factual allegations speak to the "mal-positioned" nature of the pacemaker's ventricle lead, with "the tip being in the immediate vicinity of the tricuspid valve connecting [Plaintiff's] right atrium and right ventricle." *Id.* Without more specificity, this allegation goes to the placement of the pacemaker, rather than its design. It is undisputed that Defendant did not implant the pacemaker and had no control over how the device was implanted. Accordingly, the court determines that the *res ipsa loquitur* element of "exclusive control" is lacking. Moreover, Plaintiff's theory of causation is deficient. Plaintiff has not alleged sufficient facts demonstrating that his injuries would not have occurred but for the pacemaker's design. While Plaintiff makes conclusory allegations regarding the design of the pacemaker, his specific allegations relate to the pacemaker's improper placement. Plaintiff has therefore not stated a negligence claim upon which relief can be granted, and that claim will be dismissed.

With respect to his breach of warranty claim, Plaintiff contends that he relied upon express and implied warranties made by Defendant that the pacemaker "was of merchantable quality and was safe and fit for the purpose intended when used under ordinary conditions and in an ordinary manner." *Id.* at 6 ¶ 17. Plaintiff does not allege any facts showing when and how he received notice of such warranties, nor does he allege facts showing that the pacemaker did not comport with such warranties. As discussed, Plaintiff's pleadings make clear that the alleged improper positioning of the pacemaker was a contributing cause to his injuries. Defendant did not implant the pacemaker and had no control over its positioning. It is therefore unclear whether the pacemaker was "used under ordinary conditions in an ordinary manner." *Id.* Stated simply, Plaintiff has alleged nothing

to suggest that any warranties made by Defendant were actually breached. Plaintiff has therefore not stated a breach of warranty claim upon which relief can be granted, and that claim will be dismissed.

At best, Plaintiff has alleged a sheer possibility that Defendant is liable under theories of strict liability, negligence, and breach of warranty. These allegations, however, are insufficient to state a claim upon which relief can be granted. *Iqbal*, 129 S. Ct. at 1949.

B. Federal Preemption

Defendant alternatively argues that Plaintiff's claims are preempted by federal law and must be dismissed. It is undisputed that the Medtronic Adapta Pacemaker is a Class III medical device that received approval from the Food and Drug Administration ("FDA") pursuant to that agency's premarket approval process ("PMA"). Defendant contends that claims for injuries related to devices approved in this manner are generally preempted by the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).


In *Riegel*, the Court held that "[p]remarket approval . . . imposes [federal] 'requirements'" as that term is used in Section 360k(a). 552 U.S. at 322. For the purposes of preemption, the Court determined that state common law duties constitute "requirements," and that "the duties underlying negligence, strict-liability, and implied-warranty claims" are requirements. *Id.* at 324, 327. Accordingly, *Riegel* stands for the proposition that statutory or common law causes of action that would impose different or additional duties relating to any requirement imposed by the PMA of a device are expressly preempted.

The court therefore determines that Plaintiff's claims in this case fall within the contemplation of *Riegel* because, for Plaintiff to prevail on these claims, he would necessarily have to prove that the Medtronic Adapta Pacemaker should, as a matter of law, been designed, manufactured, tested, or marketed differently from the manner approved by the FDA through the PMA process. Furthermore, Plaintiff makes no allegation that his injuries resulted from Defendant's failure to comply with the FDA-approved manufacturing process. Accordingly, the court determines that federal preemption serves as an alternative and adequate basis for dismissal of Plaintiff's claims.

IV. Conclusion

For the foregoing reasons, the court determines that Plaintiff has failed to state a claim upon which relief can be granted, or that such claims are alternatively preempted by federal law. Accordingly, the court **grants** Defendant Medtronic, Inc.'s Motion to Dismiss, and **vacates** its Order Requiring Attorney Conference and Status Report issued June 21, 2010. This action is **dismissed with prejudice**. Judgment will issue by separate document as required by Rule 58 of the Federal Rules of Civil Procedure.

It is so ordered this 25th day of June, 2010.


Sam A. Lindsay
United States District Judge